DEPARTMENT OF SOCIAL AND HEALTH SERVICES
MEDICAL ASSISTANCE ADMINISTRATION
Olympia, Washington

To: Pharmacies
All Prescribers
Managed Care Plans
Regional Administrators
CSO Administrators

Memorandum No.: 03-58 MAA
Issued: August 18, 2003

For More Information, call:
1-800-562-6188

From: Douglas Porter, Assistant Secretary
Medical Assistance Administration

Subject: **Suboxone® Added to the Expedited Prior Authorization List for the Prescription Drug Program**

Effective for the week of September 22, 2003 and after, the Medical Assistance Administration (MAA) will add Suboxone® to the Prescription Drug Program's Expedited Prior Authorization List. This numbered memorandum describes MAA's policy for Suboxone®.

FDA Approval of Suboxone®

The U.S. Food and Drug Administration approved Suboxone® for the treatment of opiate dependence in October 2002. Suboxone® contains both buprenorphine and naloxone, and it is intended for stabilization and detoxification. Suboxone® is the first narcotic drug available for the treatment of opiate dependence that can be prescribed in an office setting under the Drug Addiction Treatment Act of 2000.

Who can prescribe Suboxone®?

Under the Drug Addiction Treatment Act of 2000 (DATA), codified at 21 U.S.C. 823(g), prescription use of these products in the treatment of opioid dependence is limited to physicians who meet certain qualifying requirements and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe this product for the treatment of opioid dependence.

See attached Expedited Prior Authorization (EPA) criteria on page 5.

Who is eligible to be prescribed Suboxone®?

Effective the week of September 22, 2003, and after, clients who meet all of the following criteria are eligible to be prescribed Suboxone®:

A. The medication is prescribed by a certified physician;
B. The client is certified by the Chemical Dependency Professional (CDP), through the use of the Buprenorphine-Suboxone Authorization form [DSHS 13-720], as currently active in a state-certified, publicly-funded chemical dependency treatment program for primary opioid addiction; AND
C. The client's DSHS Medical Identification Card lists one of the following medical identifiers: CNP, CNP Children's Health, CHP-CHIP, GA-U, or LCP-MNP. Clients with any of the following identifiers are not eligible: Emergency Medical Only, Family Planning Only, or QMB-Medicare Only.

Effective the week of September 22, 2003, and after, pharmacies with a current Core Provider Agreement with the Medical Assistance Administration may be reimbursed for dispensing Suboxone® to eligible MAA clients.

Physicians, Pharmacies, and CDPs

Once the client, CDP, and physician have agreed to use Suboxone® in the treatment plan, a Buprenorphine-Suboxone Authorization form [DSHS 13-720] must be completed.

1. The CDP completes the Agency Section of the Buprenorphine-Suboxone Authorization Form [DSHS 13-720] verifying that the client is participating in a state-certified, publicly funded chemical dependency treatment program. The CDP has the client complete the Patient Section of the form and keeps a copy of the form.

2. The client takes the form to the physician, obtains a prescription for the drug from a physician, and has the physician complete the Physician Section of the Buprenorphine-Suboxone Authorization Form [DSHS 13-720]. The physician keeps a copy of the form.

3. The client takes the Buprenorphine-Suboxone Authorization Form [DSHS 13-720], along with the prescription, to a pharmacy to obtain the medication.

4. The pharmacy completes the Pharmacy Section of the Buprenorphine-Suboxone Authorization Form [DSHS 13-720] and maintains the completed form on file.

After the client obtains a prescription for Suboxone®, the physician should confer regularly with the client and the CDP to ascertain how he or she is progressing in treatment. Continued service and treatment plan reviews should be conducted to determine the appropriate level of treatment, progression with the individual treatment plan, and eligibility for take-home medication. The CDP will document the client's participation and progress in Suboxone® therapy in the client's treatment plan and progress notes.

Certified physicians must authorize Suboxone® prescriptions for no more than a 14-day supply at a time. Prescriptions for each 14-day supply may be reordered only after a recheck of urine drug screens for benzodiazepines, amphetamine/methamphetamine, cocaine, methadone, opiates, and barbiturates is performed.

The prescriber must fax the pharmacy with confirmation that the drug screen has been completed to release the next 14-day supply and retain the fax in the client's file.

Urinalysis

- Urinalysis testing necessary for medical purposes must be ordered by a physician and billed to MAA.
- Non-medical urinalysis testing for detoxification and outpatient chemical dependency treatment is an allowable expense and billed through the county contract.
- Non-medical urinalysis testing for residential chemical dependency treatment is an allowable expense and billed through the DSHS Division of Alcohol and Substance Abuse's (DASA's) residential contract.

Liver function tests must be performed and monitored periodically to guard against buprenorphine-induced hepatic abnormalities.

Pharmacy

To receive reimbursement for filling Suboxone® prescriptions, pharmacies are required to obtain and keep a record of the Buprenorphine-Suboxone Authorization form [DSHS 13-720]. This form must be signed by the client's CDP who attests by their signature that the client is currently participating in treatment. The prescribing physician's signature must be on the form as well. An example of the Buprenorphine-Suboxone Authorization form [DSHS 13-720] is attached. **To download a copy of DSHS form 13-720, go to:**
http://www.wa.gov/dshs/dshsforms/forms/eforms.html

Suboxone® is recommended to be used for up to six months only; therefore, prescriptions are limited to a period of six months. The medication is limited to a 14-day supply on each fill. Urine drug screens for benzodiazepines, amphetamine/methamphetamine, cocaine, methadone, opiates, and barbiturates must be done before each Suboxone® prescription is dispensed. In order to release the next 14-day supply, the prescriber must fax the pharmacy with confirmation that the drug screen has been completed. Pharmacies must retain the fax in the client's file. For detailed procedures, please see the attached instructions for completing the Buprenorphine-Suboxone Authorization form [DSHS 13-720].

Resources

MAA recommends that physicians and counselors review the literature on the use of this medication. Additional information is available from the following:

- FDA info web http://www.fda.gov/cder/drug/infopage/subutex_suboxone/default.htm
- CSAT Toll Free buprenorphine Info line 1-866-BUP-CSAT
- CSAT web site & Physician locator http://www.buprenorphine.samhsa.gov/
- Suboxone® information web site http://www.suboxone.com/Suboxone/
- Suboxone® Clinical Info Hotline 1-877-SUBOXONE

Replacement Pages

MAA will publish a complete update to the Expedited Prior Authorization List (Section H of MAA's Prescription Drug Program Billing Instructions) under Numbered Memoranda 03-61 MAA. The updated list will reflect the addition of Suboxone® among other updates that will be explained in Numbered Memoranda 03-61 MAA.

To view and/or download MAA's Billing Instructions and Numbered Memoranda, go to: http://maa.dshs.wa.gov (Click on "Provider Publications/Fee Schedules.)

Addition to Expedited Prior Authorization List

Drug	Code	Criteria
Suboxone® *(Buprenorphine/ Naloxone)*	**019**	Before the code is allowed, the patient must meet all of the following criteria. The patient: • Is 16 years of age or older; • Has a DSM-IV-TR diagnosis of opioid dependence ; • Is psychiatrically stable or is under the supervision of a mental health specialist; • Is not abusing alcohol, benzodiazepines, barbiturates, or other sedative-hypnotics; • Is not pregnant or nursing; • Does not have a history of failing multiple previous opioid agonists treatments and multiple relapses; • Does not have concomitant prescriptions of azole antifungal agents, macrolide antibiotics, protease inhibitors, phenobarbital, carbamazepine, phenytoin, and rifampin, unless dosage adjusted appropriately; and • Is enrolled in a state-certified chemical dependency treatment program. **Limitations:** • No more than a 14-day supply may be dispensed at a time; • Urine drug screens for benzodiazepines, amphetamine/methamphetamine, cocaine, methadone, opiates, and barbiturates must be done before each prescription is dispensed. The prescriber must fax the pharmacy with confirmation that the drug screen has been completed to release the next 14-day supply. The fax must be retained in the pharmacy for audit purposes; • Liver function tests must be monitored periodically to guard against buprenorphine-induced hepatic abnormalities; and • Clients may receive up to six months of buprenorphine treatment for detoxification and stabilization. **Note:** A Buprenorphine-Suboxone Authorization Form [DSHS 13-720] must be on file with the pharmacy before the drug is dispensed (see attached sample).

THIS IS A BLANK PAGE.

Washington State Department of Social & Health Services

BUPRENORPHINE – SUBOXONE AUTHORIZATION

AGENCY SECTION

DIVISION OF ALCOHOL AND SUBSTANCE ABUSE (DASA) CERTIFIED CHEMICAL DEPENDENCY TREATMENT AGENCY	AGENCY NUMBER (USE NUMBER IN GREENBOOK DIRECTORY OF CERTIFIED SERVICES IN WASHINGTON)

The certified chemical dependency treatment agency listed above verifies that the patient listed below is sixteen years of age or older; alcohol or opiate dependent, with opiate dependency as the primary addiction; and has been admitted to publicly funded chemical dependency treatment. The patient's Chemical Dependency Professional (CDP) hereby recommends the use of Buprenorphine as a part of the patient's treatment plan as indicated by signature below.

CDP'S SIGNATURE	DATE	CDP'S PRINTED NAME	CDP'S TELEPHONE NUMBER

PATIENT SECTION

PATIENT'S NAME	PATIENT'S MAA PIC NUMBER	DATE ADMITTED TO CHEMICAL DEPENDENCY TREATMENT

☐ Opiate Dependent

PATIENT AUTHORIZATION FOR DISCLOSURE OF CONFIDENTIAL INFORMATION

I, _____(print patient's name) authorize the certified chemical dependency treatment agency indicated above to disclose patient identifying information, my status as a patient, and their treatment recommendation to my physician and the pharmacy indicated below for obtaining a prescription for Buprenorphine.

PRINT PHYSICIAN'S NAME	PRINT PHARMACY'S NAME

I understand that my alcohol and/or drug treatment records are protected under Federal and State Confidentiality regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 Code of Federal Regulations, Part 2 and the Health Insurance Portability and Accountability Act of 1996, 45 Code of Federal Regulations, Parts 160 and 164, and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it, and that in any event this consent expires automatically as follows: **either 90 days from the date signed, or the following specific date, event, or condition upon which this consent expires:**

_____. I understand that generally _____ **(insert name of certified chemical dependency agency)** may not condition my treatment on whether or not I sign a consent form, but that in certain limited circumstances I may be denied treatment if I do not sign a consent form.

PATIENT'S SIGNATURE	DATE	SIGNATURE OF PARENT, GUARDIAN, OR AUTHORIZED REPRESENTATIVE (WHEN REQUIRED)	DATE

PHYSICIAN SECTION

PHYSICIAN'S NAME	TELEPHONE NUMBER	MEDICAID PROVIDER NUMBER OR DEA ID NUMBER

ADDRESS

Date ordered by physician:	Proposed treatment start date:

PHARMACY SECTION

PHARMACY'S NAME	MEDICAID PROVIDER NUMBER

I have received a prescription for Buprenorphine for the patient named above from the patient's physician and have filled the prescription as authorized. I understand that reimbursement for the Medical Assistance Administration (MAA) for Buprenorphine shall only be made under the following conditions.

1. The medication is provided as part of a comprehensive treatment program as verified by the certification provided above.
2. Payment for the medication is limited to six months of continuous use. The medication is limited to a fourteen-day (14-day) supply on each fill.
3. The pharmacy shall include the prescribing physician's MAA Medical Provider number on the MAA billing form.
4. Record of this certification shall be kept on file at the pharmacy for MAA audit purposes. Prescriptions reimbursed by the MAA for Buprenorphine without this certification record on file shall be considered an overpayment.

PHARMACIST'S SIGNATURE	DATE	TELEPHONE NUMBER

ADDRESS

BUPRENORPHINE – SUBOXONE AUTHORIZATION
FORM INSTRUCTIONS

If a patient and "qualified physician" agree that Buprenorphine may be an appropriate chemical dependency treatment and wish to seek payment for a prescription for the medication, to be made by the state, a Buprenorphine Authorization form must be completed.

1. Complete the **PHYSICIAN SECTION**:
   - ?? Enter the name of the physician and the physician's Medicaid Provider number or their DEA identification number that specifically authorizes office-based treatment.
   - ?? Enter the date the physician determined the patient was in need of Buprenorphine treatment and the proposed treatment start date.

2. Complete the **AGENCY SECTION**:
   - ?? Enter the name of the certified chemical dependency treatment agency and the agency's 8-digit certification agency identification number found in the Directory of Certified Chemical Dependency Treatment Services in Washington State (commonly known as the Greenbook) published by the Division of Alcohol and Substance Abuse.
   - ?? The patient's chemical dependency professional signs and dates the form at the end of this section.

3. Complete the **PATIENT SECTION**:
   - ?? Enter the patient's name.
   - ?? Enter the patient's Medical Assistance Administration Patient Identification Code (PIC) number.
   - ?? Enter the date the patient was admitted to Buprenorphine treatment
   - ?? A DSM-IV-TR diagnosis for opiate dependency (heroin or other short-acting opioids).

   Complete the **Patient Authorization for Disclosure of Confidential Information SECTION**, being sure to discuss this disclosure with the patient and by having him/her sign and date the disclosure statement section.

4. Give the patient copies of the Buprenorphine Authorization form to take to his/her physician, primary Chemical Dependency Professional (CDP), and then to the pharmacy to obtain the prescription.
   - ?? The physician should keep a copy of the Buprenorphine Authorization Form for the medical record.
   - ?? The CDP at the chemical dependency treatment agency should keep a copy for the patient's record.

5. The Pharmacist will complete the **PHARMACY SECTION**: The Pharmacist keeps the final copy on file at the pharmacy for future Medical Assistance Administration audit purposes.

6. The physician, the patient, the CDP at the chemical dependency treatment agency, and the Pharmacist should all keep copies of the Buprenorphine Authorization form.